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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,180	01/18/2007	Bruno Balay	0512-1319	5568
466 7590 08/02/2010 YOUNG & THOMPSON 209 Madison Street Suite 500 Alexandria, VA 22314			EXAMINER HOBAN, MELISSA A	
			ART UNIT 3738	PAPER NUMBER
			NOTIFICATION DATE 08/02/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

### Office Action Summary

**Application No.**

10/566,180

**Applicant(s)**

BALAY ET AL.

**Examiner**

MELISSA HOBAN

**Art Unit**

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-13, 18-21, 23 and 24 is/are rejected.
- 7) ☒ Claim(s) 4 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. The Amendment filed 4/26/2010 has been entered. The previous objection to the oath/declaration is withdrawn in light of the newly submitted oath/declaration filed 5/18/2010. The previous objection to the claims is withdrawn in light of applicant's amendments. The previous rejection under 35 USC 112 2<sup>nd</sup> paragraph is withdrawn in light of applicant's amendments. Claims 1-13 and 18-24 are currently pending in this application.

#### *Claim Objections*

2. Claim 24 is objected to because of the following informalities: Claim 24 recites "the threads are is", in line 2. It appears that this is a grammatical error and that the word "is" should be deleted. Appropriate correction is required.

#### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3, 21, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 3 and 21 recite the limitation "the coating" in line 2 of each. The examiner is unsure whether applicant is referring to -- **the thick coating** --, as recited in claims 2 and 20.

6. Claim 24 recites the limitation "the acetabular bone site" in line 3. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 5, 6, 18, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,883,491 to Mallory et al. (Mallory).

Mallory teaches a porous-coated, threaded acetabular cup (screw cup; 10) including a self-tapping screw thread (screwing means; 16) (col. 2, lines 46-56 and col. 3, lines 36-38). The thread (16) is formed on the outer surface of the body (18) by milling the surface and is preferably a spherical thread that includes leading edges (30) which are sufficiently sharp for the thread to be self-tapping (col. 3, lines 55-61 and fig. 1). The threads (screwing means; 16) are located at a periphery or in a tropical/equatorial zone of the cup and are intended to be introduced into bone material of the acetabulum during a screwing action, as claimed by applicant. Mallory also teaches that the thread (16) is interrupted by a plurality of porous-coated columns (24) and a porous-coated dome (12) (col. 4, lines 4-25). The examiner takes the position that the porous-coated columns (24) meet the limitation of zones or troughs or recesses of threads that are left free in the screwing means. Therefore, Mallory clearly teaches a coating carried by the cup, which coating facilitates osteointegration, wherein the coating is thick on the convex portions of an outer surface of the cup (24, 20, and 12) and the coating is absent on screw reliefs or threads (16 and 26). The examiner also

takes the position that at least the sharpness of the thread (screw reliefs; 16) meets the limitation of having a rough surface (fig. 3), as claimed by applicant.

With regard to the functional language used throughout the claims (see claims 6 and 24), the examiner notes that the device of Mallory is fully capable of meeting the claimed functions, including that the screwing means is arranged in order to traumatize as little as possible an acetabular bone site, in which the threads are introduced, and in order to have a maximum convex surface-area, by having troughs (24) between sides of threads (16) in order to facilitate osteointegration by contact osteogenesis and remodeling under stress, the screw reliefs (16) being arranged in order to apply self-tapping cutting effect during the screwing action and an effect involving compression of sponge-like bone, particularly since it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 2, 3, 19, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mallory in view of US Patent Application Publication No. 2003/0050705 A1 to Cueille et al. (Cueille).

Mallory teaches the invention substantially as claimed according to claims 1 and 18. However, Mallory does not teach a thickness of the thick coating being from 100 to 200 micrometers or being of an order of 150 +/- 35 micrometers.

Cueille teaches an acetabular cup for use in a total hip prosthesis comprising an inner bearing surface portion (21), an outer bone-interface layer (22) and a hydroxyapatite (HA) coating (23). The surface finish of the bone interface layer can be structured, by machining or any other method, before the HA coating is applied. Cueille also teaches that the hydroxyapatite coating is sprayed onto the porous surface (23) with a preferred thickness between 0.020 and 0.2 millimeters (20 and 200 micrometers) thick (paragraph 0023), for the purpose of allowing for bone-growth resulting in firm attachment (paragraph 0012).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the porous-coated portions of Mallory to specify a thickness being from 100 to 200, more specifically being of an order of 150 +/- 35 micrometers, in order to allow for bone-growth resulting in firm attachment, and also since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Further, it would have been obvious to specify this range of thickness, particularly in view of the lack of any disclosed criticality of the claimed limitations (see page 3 of applicant's specification which clearly states that these thicknesses are not limiting and that they are dependent on the type and quality of the osteointegrating coating).

11. Claims 7, 8, 11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mallory.

Regarding at least claim 7

Mallory teaches the invention substantially as claimed according to claim 6. Though Mallory does not appear to explicitly teach a proportion of thread width relative to a thread pitch from 0.2 to 0.5, the examiner takes the position that it would have been obvious to include such proportions, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. It also would have been obvious particularly in view of the lack of any disclosed criticality of the claimed limitation (see page 4 of applicant's specification which implies that this proportion is not material to the patentability of the invention).

Regarding at least claim 8

Mallory teaches the invention substantially as claimed according to claim 1. Though Mallory does not appear to explicitly teach angles of the threads with respect to the outer surface of the cup, Mallory does teach that the cup includes a self-tapping screw thread having a cross-section which appears to be asymmetrical in a diametral plane, at least to the same extent applicant's is, with a smaller angle at the polar side of the thread and a greater angle at an equatorial side (fig. 3).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Mallory to include specifics about the threads, such as angles, in order to include threads having a size, thickness, and height adapted

to the size of the socket component for use so that the operator, during surgery, can select a cup matched to the quality of bone material in the pelvic region (see for example US Patent No. 5,443,520 to Zweymuller et al.). It also would have been obvious to specify the angles of the threads on the polar side and on the equatorial side, particularly in view of the absence of any disclosed criticality of the claimed limitations. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding at least claims 11 and 13

Mallory teaches the invention substantially as claimed according to claim 1. Mallory also appears to meet the limitation of having a regular threading pitch, as claimed by applicant, since the definition of regular is: conforming to a standard or pattern, which Mallory's threading pitch clearly does. Further, the threading of Mallory is spherical and appears to have a constant pitch.

12. Claims 9-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mallory in view of US Patent No. 5,147,407 to Tager (Tager).

Mallory teaches the invention substantially as claimed according to claim 1. However, Mallory does not explicitly teach that the crests of threads are relieved or that the leading edge is inclined.

Tager teaches a prosthetic cup member having an outer surface with coaxial threads interrupted by grooves extending transversely to the thread. The threads are self-tapping threads and are formed to permit the threaded outer shell to be screwed



into the bone (abstract). Tager further teaches that openings (inclined grooves; 11) are milled at an angle with respect to the axis and at an angle with respect to the radius, i.e. the walls of the openings are inclined towards the rotational direction of outer shell (10) (col. 3, lines 1-9). The discrete thread portions (12) form a plurality of rows (zones; 13) at an angle to the axis of outer shell (10) between openings (11). Since the device taught by Tager is made in the same way as applicant's, it is inherent that it also includes crests with leading edges of threads that are radially higher than the remainder of the crest, and which leading edges are themselves inclined by being formed by a milling pass, as claimed by applicant.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Mallory to include crests of threads that are relieved or that the leading edge is inclined in order to facilitate insertion of the cup and improve its anchoring after emplacement, as taught by Tager (col. 2, lines 14-20).

#### ***Allowable Subject Matter***

13. Claims 4 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA HOBAN whose telephone number is (571)270-5785. The examiner can normally be reached on Monday-Friday 8:00AM-5:00PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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MH

/Bruce E Snow/

Primary Examiner, Art Unit 3738